

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ALMIRALL, LLC,

Plaintiff,

v.

ZYDUS PHARMACEUTICALS (USA) INC. and
ZYDUS WORLDWIDE DMCC,

Defendants.

C.A. No. 20-343

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Almirall, LLC (“Almirall”), by its undersigned attorneys, for its Complaint against Defendants Zydus Pharmaceuticals (USA) Inc. (“Zydus USA”) and Zydus Worldwide DMCC, (“Zydus Worldwide,” together with Zydus USA, “Zydus”), alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement brought under the United States Patent Act and the Hatch-Waxman Act, based upon Zydus’s submission of Abbreviated New Drug Application No. 214019 (the “Zydus ANDA”) with the United States Food and Drug Administration (“FDA”).

2. By the Zydus ANDA, Zydus seeks approval to market a generic dapsone gel, 7.5% drug product (the “ANDA Product”) prior to the expiration of United States Patent No. 9,517,219 (“the ’219 patent”), which covers, *inter alia*, the use of Almirall’s ACZONE® Gel, 7.5% drug product, and which is listed accordingly in the FDA’s publication, “Approved Products with Therapeutic Equivalence Evaluations” (the “Orange Book”).

PARTIES

3. Plaintiff Almirall is a limited liability company organized and existing under the laws of the Commonwealth of Pennsylvania, having a place of business at 707 Eagleview Boulevard, Suite 200, Exton, Pennsylvania 19341.

4. Defendant Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

5. Defendant Zydus Worldwide DMCC is a corporation organized and existing under the laws of United Arab Emirates, having a principal place of business at Armada Tower 2, P2, Cluster P, 9 Floor, Office 908, Al Thanyah 5, Hadaeq Mohammed Bin Rashid, Dubai, United Arab Emirates.

JURISDICTION AND VENUE

6. This civil action for infringement of the '219 patent arises under 35 U.S.C. § 271 and 21 U.S.C. § 355(j).

7. Original jurisdiction is vested in this Court over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. Zydus USA and Zydus Worldwide operate as a single integrated business. Zydus Worldwide and Zydus USA each act as an agent of the other and work together to, *inter alia*, develop, manufacture, obtain regulatory approval, market, sell, and distribute generic copies of branded pharmaceutical products throughout the United States, including this judicial district.

9. Zydus USA is registered to do business in the State of New Jersey under Entity Identification Number 0100915422.

10. Zydus USA is registered with the New Jersey Department of Health as a drug wholesaler under Registration Number 5003171.

11. Upon information and belief, Zydus USA, directly or thought its affiliates and agents, is present in, and conducts the business of and derives revenue from, *inter alia*, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products, in the State of New Jersey.

12. Upon information and belief, Zydus Worldwide, directly or thought its affiliates and agents, is present in, and conducts the business of and derives revenue from, *inter alia*, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products, in the State of New Jersey.

13. Zydus USA has previously consented to and availed itself of the jurisdiction of this Court by, *inter alia*, asserting claims and defenses in other civil actions initiated in this jurisdiction.

14. Zydus Worldwide has previously consented to and availed itself of the jurisdiction of this Court by, *inter alia*, asserting claims and defenses in other civil actions initiated in this jurisdiction.

15. Zydus USA's affiliations with the State of New Jersey are such as to render Zydus "at home" in this jurisdiction.

16. Zydus Worldwide's affiliations with the State of New Jersey are such as to render Zydus "at home" in this jurisdiction.

17. Upon information and belief, Zydus, directly or thought its affiliates and agents, participated, in the State of New Jersey, in the preparation and/or filing of the Zydus ANDA, causing injury to Plaintiff Almirall.

18. In its business of developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products, Zydus has purposefully directed

activities at residents of the State of New Jersey.

19. This Court has personal jurisdiction over Zydus USA.
20. This Court has personal jurisdiction over Zydus Worldwide.
21. Almirall's assertions of personal jurisdiction are reasonable and fair.
22. By its incorporation, Zydus USA resides in the State of New Jersey.
23. At 73 Route 31 North, Pennington, New Jersey 08534, and elsewhere in the State, Zydus has a regular and established place of business.
24. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) and/or 28 U.S.C. § 1391.

THE PATENT-IN-SUIT

25. On December 13, 2016, the United States Patent and Trademark Office issued the '219 patent, entitled "Topical Dapsone and Dapsone/Adapalene Compositions and Methods for Use Thereof," a copy of which is attached as **Exhibit A** to this Complaint.

26. Plaintiff Almirall owns all rights, title, and interest in the '219 patent.

ACZONE® GEL, 7.5%

27. Almirall is the holder of approved New Drug Application No. 207154 (the "ACZONE® NDA") for a topical drug product used to treat acne vulgaris, and containing, *inter alia*, 7.5% by weight of the active pharmaceutical ingredient, dapsone. The FDA granted approval of the ACZONE® NDA on February 24, 2016.

28. Almirall markets and sells the subject product of the ACZONE® NDA under the trade name ACZONE® Gel, 7.5%.

29. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '219 patent is listed in the Orange Book with respect to the ACZONE® NDA and ACZONE® Gel, 7.5%.

THE ZYDUS ANDA

30. Zydus Worldwide is the owner of the Zydus ANDA.

31. On information and belief, Zydus submitted, or caused to be submitted, the Zydus ANDA to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), in order to obtain approval to market the ANDA Product as a generic version of ACZONE® Gel, 7.5%.

32. On information and belief, the Zydus ANDA refers to and relies upon the ACZONE® NDA and contains data that, according to Zydus, demonstrate the bioequivalence of the ANDA Product and ACZONE® Gel, 7.5%.

33. On or about November 26, 2019, Almirall received from Zydus, via Federal Express, a letter titled “Re: ACZONE® (dapsone) gel, 7.5%; ANDA No. 214019; U.S. Patent Nos. 9,161,926 and 8,517,219” (the “Notice Letter”).

34. The Notice Letter provides notice that Zydus submitted to the FDA the Zydus ANDA, which included a certification by Zydus, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the ’219 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the ANDA Product prior to the patent’s expiration (“Zydus’s Paragraph IV Certification”).

35. Zydus attached a memorandum (or “Detailed Statement”) to its Notice Letter by which it alleged factual and legal bases for its Paragraph IV Certification. Zydus’s Notice Letter provides allegations that the claims of the ’219 patent are invalid and/or will not be infringed by acts in relation to the ANDA Product as described in the Zydus ANDA.

36. The Notice Letter provides that Zydus seeks approval to market the ANDA Product before the ’219 patent expires.

CLAIM FOR INFRINGEMENT OF THE '219 PATENT

37. Almirall realleges and incorporates by reference Paragraphs 1 through 36 of this Complaint.

38. The Zydus ANDA is an application for FDA approval of Zydus to market the ANDA Product for, *inter alia*, use by physicians treating, and patients having, acne vulgaris.

39. Use of the ANDA Product as described in the Zydus ANDA is a method of treatment claimed in the '219 patent.

40. The submission by Zydus to the FDA of the Zydus ANDA was an act of infringement of the claims of the '219 patent.

41. The claims of the '219 patent are not invalid.

42. The claims of the '219 patent are infringed by acts in relation to the ANDA Product as described in the Zydus ANDA.

43. Approval of the Zydus ANDA prior to the expiration of the '219 patent will injure Plaintiff Almirall as owner of the patent, holder of the ACZONE® NDA, and distributor and seller of ACZONE® Gel, 7.5% in the United States.

44. An actual case or controversy exists between Almirall and Zydus.

45. Almirall will be harmed substantially and irreparably if Zydus is not enjoined from infringing the '219 patent.

46. Almirall has no adequate remedy at law.

47. Almirall is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Almirall prays for judgment in its favor and against Zydus and respectfully requests the following relief:

- (a) A judgment that Zydus has infringed one or more claims of the '219 patent under 35 U.S.C. § 271(e)(2);
- (b) An order, pursuant to 35 U.S.C. §271(e)(4)(A), that the effective date of any approval of the Zydus ANDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)), shall not be earlier than the expiration of the '219 patent, including any extensions, adjustments, and exclusivities;
- (c) A grant, pursuant to 35 U.S.C. § 271(e)(4)(B), of an injunction against Zydus, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, preventing the commercial manufacture, use, offer to sell, or sale of the ANDA Product within the United States, or the importation the ANDA Product into the United States, prior to the expiration of the '219 patent, including any extensions, adjustments, and exclusivities;
- (d) Attorneys' fees in this action, as an exceptional case pursuant to 35 U.S.C. § 285;
- (e) Costs and expenses in this action; and
- (f) Such other and further relief as this Court may deem just and proper.

Respectfully submitted,

GIBBONS P.C.

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